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10/507,416	05/27/2005	Marie-Claire Grosjean-Cournoyer	05394.0021	6878
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER JOIKE, MICHELE K	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 07/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/507,416

Applicant(s)

GROSJEAN-COURNOYER ET AL.

Examiner

Michele K. Joike, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 21-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/17/04, 12/09/04, 12/16/04, 02/03/05.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group 80 in the reply filed on June 12, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-13 and 21-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 12, 2007.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

### ***Specification***

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink

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and/or other form of browser-executable code. See MPEP § 608.01. The hyperlinks are found in paragraphs 109, 209, 212 and 232-235.

Appropriate correction is required.

### ***Claim Objections***

Claims 14 and 15 are objected to because of the following informalities: Claim 14 is missing an article between the words "in" and "essential" in lines 6 and 7. In line 7, *in vivo* needs to be italicized, and in line 1 of claim 15, *Aspergillus* needs to be italicized. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the diploid transformant strain" in line 5. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a method using an *impala 160* transposon or a derivate thereof for transposon mutagenesis. The claims read on a broad genus of possible derivatives of the transposon.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the claimed invention. In the instant case, the specification does not sufficiently describe a representative number of mutations or alterations (derivatives) to the *impala 160* transposon that would allow it to still function as a transposon.

The specification does not teach how to mutate or alter the sequence in order to maintain the function of the transposon. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification does not disclose any derivatives of the transposon.

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The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the art that allows one to envision a representative number of derivatives by disclosing structural or functional features of the possible derivatives so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot consult the art at the time of filing to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the state of the art at the time of filing teaches a structure-function relationship for a representative number of derivatives. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that CEA 225, CEA 226 and CEA 227 are required to practice the invention. As such, the strains must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strains. In the instant case, the process to generate the

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strains that is disclosed in the specification does not appear to be repeatable, nor does it appear the strains are readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

a) during the pendency of the application, access to the invention will be afforded to the

Commissioner upon request;

b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;

d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

e) the deposit will be replaced if it should ever become inviable.

Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-16 and 18 are rejected under 35 U.S.C. 103(a) as being obvious over US 2003/0129733 in view of US 6,617,163.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

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application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Applicants teach a method for locating at least one gene essential for the growth of a haploid fungus, said method comprising the following successive steps: generation of diploid strain from fungal haploid strain; mutagenesis of said diploid strain; haploidization of the diploid transformant strain, in selection conditions such that the absence of haploid progeny is indicative of mutagenesis occurring in essential gene; wherein said mutagenesis is an *in vivo* transposon mutagenesis. The haploid fungus is *Aspergillus fumigatus*. The transposon is an *impala 160* transposon.

US 2003/0129733 (see entire document, specifically paragraphs 7, 8, 10-18, 36, 41, 43, 44, 47, 50-53, 141 and 163) teaches a method of mutating cells for locating at least one gene essential for the growth of a haploid fungus, by generating a diploid strain from a fungal haploid strain, mutagenesis of the diploid strain, and haploidization of the diploid transformant strain, in selection conditions such that the absence of haploid progeny is indicative of mutagenesis occurring in an essential gene. The haploid fungus can be *Aspergillus fumigatus*. Mutagenesis can occur by insertional mutagenesis.

US 2003/0129733 does not teach insertional mutagenesis with the *impala 160* transposon.

US 6, 617,163 (specifically columns 1, 2, 5, 6, 8, 9 and Ex. 1) teaches the use of the *impala 160* transposon for insertional mutagenesis in *Aspergillus fumigatus*.

The ordinary skilled artisan, desiring to use the *impala 160* transposon in a method for locating at least one gene essential for the growth of a haploid fungus, said method comprising the following successive steps: generation of diploid strain from fungal haploid strain mutagenesis of said diploid strain; haploidization of the diploid transformant strain, in selection conditions such that the absence of haploid progeny is indicative of mutagenesis occurring in essential gene; wherein said mutagenesis is an *in vivo* transposon mutagenesis, would have been motivated to combine the teachings of US 2003/0129733 of a method of mutating cells for locating at least one gene essential for the growth of a haploid fungus, by generating a diploid strain from a fungal haploid strain, mutagenesis of the diploid strain, and haploidization of the diploid transformant strain, in selection conditions such that the absence of haploid progeny is indicative of mutagenesis occurring in an essential gene, with the teachings of US 6, 617,163 teaching insertional mutagenesis with the *impala 160* transposon, because US 6, 617,163 states that fungal transposons are valuable tools in insertional mutagenesis. It would have been obvious to one of ordinary skill in the art to use *in vivo* transposon mutagenesis because US 6, 617,163 teach that insertional mutagenesis is effective for identifying novel genes of interest. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 20 is rejected under 35 U.S.C. 103(a) as being obvious over US 2003/0129733 in view of US 6,617,163 and in further view of Klinner et al.

Claim 20 teaches the use of benomyl in the media.

US 2003/0129733 and US 6, 617,163 teach all of the limitations as described above. However they do not teach the use of benomyl in the media. (US 2003/0129733 teaches the use of mitotic inhibitor, fluorophenylalanine.)

Klinner et al (Current Micro. 11: 241-246, 1984, specifically, p. 241) teach using benomyl in the selective medium.

The ordinary skilled artisan, desiring to use benomyl in the medium in a method for locating at least one gene essential for the growth of a haploid fungus, said method comprising the following successive steps: generation of diploid strain from fungal haploid strain mutagenesis of said diploid strain; haploidization of the diploid transformant strain, in selection conditions such that the absence of haploid progeny is indicative of mutagenesis occurring in essential gene; wherein said mutagenesis is an *in vivo* transposon mutagenesis, would have been motivated to combine the teachings of US 2003/0129733 of a method of mutating cells for locating at least one gene essential for the growth of a haploid fungus, by generating a diploid strain from a fungal haploid strain, mutagenesis of the diploid strain, and haploidization of the diploid transformant strain, in selection conditions such that the absence of haploid progeny is indicative of mutagenesis occurring in an essential gene, with the teachings of US 6, 617,163 teaching insertional mutagenesis with the *impala 160* transposon, and with Klinner et al teaching using benomyl in the selective medium, because Klinner et al states that

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benomyl induces haploidization. It would have been obvious to one of ordinary skill in the art to use benomyl because Klinner et al teach that fluorophenylalanine and benomyl induce frequent mitotic segregation. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

***Allowable Subject Matter***

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Michele K Joike, Ph.D.  
Examiner  
Art Unit 1636

  
NANCY VOGEL  
PRIMARY EXAMINER